

IMPROVING DECISION MAKING IN CANCER TREATMENT WITH A MIX OF COST-EFFECTIVENESS ANALYSIS AND ETHICAL PERSPECTIVE: USA EXAMPLE

MALİYET ETKİNLİK VE AHLAKİ PERSPEKTİF KARMASI İLE KANSER TEDAVİSİNDE TERCİH GELİŞTİRME: ABD ÖRNEĞİ

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Abstract

In the world, healthcare costs have been on the rise and getting larger share in the economic pie. Since we have limited resources, allocation of resources becomes more of an issue. Cancer is one of most leading causes of death in the world and each year, money spent on cancer treatment goes up. However, today new cancer drugs and treatment only provide narrow benefit with very high costs. Therefore, only limited number of people enjoys getting the treatment and fewer treatment or drugs are reimbursed. In addition, many countries do not have a standard to decide whether a cancer drug or a treatment will be covered. Considering both economic efficiency (cost-effectiveness analysis) and ethical issues together during the decision process is of great importance so as to distribute health resources fairly and maximize health benefits.

Keywords: Cancer treatment and drugs, reimbursement process, cost-effectiveness analysis, health ethics, resource allocation

Özet

Dünyada sağlık harcamaları yükselme eğilimdedir ve ekonomik pastadan her geçen gün daha büyük pay almaktadır. Kaynakların dağıtımı, kısıtlı kaynaklar altında önem kazanmaktadır. Kanser, ölümün önde gelen sebeplerinden biridir ve her geçen yıl kanser tedavisine harcanan para artış göstermektedir. Bugün, kanser tedavisi ve ilaçları, yüksek maliyetine rağmen kısıtlı bir fayda sağlamaktadır. Bu yüzden,

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sadece kısıtlı sayıda insan tedaviden faydalanmakta ve az sayıda tedavi ve ilaç geri ödeme kapsamındadır. Ayrıca, birçok ülke bir ilaç ya da tedavinin geri ödenip ödenmemesine karar verme konusunda bir standarda sahip değildir. Sağlık faydalarını maksimize etmek ve kaynakları adil dağıtmak için geri ödeme sürecinde hem ekonomik etkililik (maliyet etkinlik analizi) hem de ahlaki etkenler büyük önem arz etmektedir.

Anahtar Kelimeler: Kanser tedavisi ve ilaçları, geri ödeme süreci, maliyet etkinlik analizi, sağlık etiği, kaynak dağıtımı

Introduction

Healthcare accounts for a remarkably large share of the world's economic pie in most of the countries, particularly in the United States (U.S.). Each year health-related spending grows, often outpacing spending on other goods and services. As a country spends on more on health, it has to sacrifice to allocate resources on other industries. Of all the nations, the U.S. spending for healthcare comes first and it reached \$2.7 trillion in the aggregate, \$8,680 per person, and 17.9% of GDP in 2011 (Centers for Medicare and Medicaid Services, 2013).

Cancer ranks second among common causes of death in the U.S as in many countries (Scnipper et al, 2010). Furthermore, it is increasing in prevalence because of aging of the population and the limited number of successful prevention strategies. Along with the rising costs of diagnostics and treatments, the money spent on cancer care between 1990 and 2004 more than doubled, increasing from \$27.5 billion to \$72.1 billion and constituting approximately 5% of the national health spending (National Cancer Institute, 2007). Likewise, even with quite young population Turkey nearly spends 3% of its total publicly financed health spending on cancer treatment.²

Today many cancer drugs and treatment provide only limited benefits but at very high costs. Those costs exert great pressure on the budgets of the health plans and government programs with their limited

2 Social Security Institution of Turkey Health data.

budget. Most importantly, many countries do not have a standard on the decision process for their benefit package covered in the cancer treatment. I argue that decision makers have to take into account both economic efficiency (cost-effectiveness analysis) and ethical issues together during the decision whether to cover the cancer treatments or drugs. Otherwise, limited resources will be wasted and hence health outcomes will worsen, and health resources will not be distributed equitable.

Resource Allocation in Health

Resource allocation involves the distribution of goods and services among competing programs or people. Resources to improve healthcare have always been scarce, in the sense that health must compete with other social goals such as education, defense, and transportation (Brock, 1997). It is not possible to provide all resources to healthcare without sacrifices in other important social goods. It follows from resource scarcity that some form of healthcare rationing is inevitable. Brock (1997) defines rationing “as a mean of allocating healthcare resources that denies to some persons some potentially beneficial health care”. That rationing can take different forms. For instance, in countries with a national health system it is done through some form of global budgeting for healthcare whereas in the U.S. much rationing is by ability to pay.

There are several broad value questions that arise in the allocation of healthcare resources. The first one is how much of a society’s resources should go to healthcare as opposed to other goods and services. With the national healthcare system, this question can be addressed as a political issue by setting a global budget for society’s health expenditures. The U.S. government spent \$1.1 trillion (roughly 18% of the total budget) out of \$6.1 trillion government budget in 2011.³ This amount is quite high compared to other Organization for Economic Cooperation and Development countries. Then, the next question is how much of total healthcare resources should go to

3 http://www.usgovernmentspending.com/total_spending_2011USrn

different health care needs and patients. I think this question is really important when deciding how to prioritize cancer treatments and drugs. In order to answer this question we need to understand two broad standards on healthcare resource allocation: cost-effectiveness and ethical perspective.

Cost-effectiveness and Ethical Perspective

Firstly, cost-effectiveness analysis (CEA) is an attempt to measure the health benefit per dollar spent. CEA highlights limited resources for health should be allocated in such a way that it maximizes the health benefits for the population. A CEA of alternative health interventions measures their respective costs and benefits to determine their relative efficiency. While costs are measured in monetary terms, benefits are measured mostly in the form of quality adjusted life years (QALYs), a measure of disease burden, including both the quality and the quantity of life lived.⁴ The QALY model requires utility independent, risk neutral, and constant proportional tradeoff behavior (Pliskin et al, 1980) and rests on the number of years of life that would be added by the intervention. Each year in perfect health is assigned the value of 1.0 down to a value of 0.0 for being death. If the extra years would not be lived in full health, for example if the patient would lose an arm, or be blind or have to use a wheelchair, then the extra life-years are given a value between 0 and 1 to account for this. Then by dividing costs to benefits, we can obtain a cost-effectiveness ratio (cost per QALY) for each health intervention, and interventions can be ranked by these ratios.

The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom (UK) has been using QALYs to measure the health benefits delivered by various treatment regimens. The NICE is believed to have a threshold of about £30,000 per QALY even though a formal figure has never been announced publicly (Devlin and Parkin, 2004). Thus, any health intervention which has an incremental cost of more than £30,000 per additional QALY gained is likely to be rejected and

4 National Institute for Health and Clinical Excellence - Measuring effectiveness and cost effectiveness: the QALY

any intervention which has an incremental cost of less than or equal to £30,000 per extra QALY gained is likely to be accepted as cost-effective. Moreover, World Health Organization announced a cost-effectiveness threshold of three times of a country's gross domestic product per capita for developing countries.

Supporters of CEA argue that since healthcare resources are inevitably limited, this analysis puts criteria and enables them to be allocated in the way that is approximately optimal for society, including most patients. On the other hand, CEA is criticized that it does not take into account equity issues such as the overall distribution of health states (Brock, 2003a). Also, many would argue that all else being equal, patients with more severe illness should be prioritized over patients with less severe illness if both would get the same absolute increase in utility. Another criticism involves age; elderly individuals are assumed to have lower QALYs since they do not have as many years to affect the calculation; so comparing a health intervention's impact on a teenager's QALYs to an older individual's QALYs may not be considered as fair (Rawl, 1971). Furthermore, specific health outcomes may also be difficult to quantify, thus making it difficult to compare all factors that may influence an individual's QALY. For example, when we compare an intervention's impact on the livelihood of a single woman to a mother of three QALYs do not consider the importance that an individual person may have for others' lives (Pinkerton et al, 2002).

I argue that CEA is a mixture of an economic analysis and ethical criterion for the evaluation of health programs although many argue that CEA do not take into account ethical issues. I advocate that cost-effectiveness is not merely an economic concern, because improving people's health is a moral concern, and allocation of resources that is not cost-effective produces fewer health outcomes than would have been possible with a different allocation. Producing more rather than fewer benefits for people is one important ethical consideration in evaluating social policies. Moreover, covering health services that are not cost-effective can lead to not financing other services generating more benefits.

Many new cancer treatments often fail to meet cost-effectiveness standards in the U.S and UK. The main causes of poor cost-effectiveness in cancer care are intellectual property patent protection on new drugs, high cost of drug development, and use of drugs having small benefit but high cost. Besides, most importantly Medicare cannot negotiate drug prices and make judgments about value of new therapies on grounds of cost-effectiveness since its standard for coverage is whether the drug is “reasonable and necessary” for the diagnosis or treatment (Fox, 2005; Brock, 2010).

Secondly, resource allocation in health should be based on ethical perspective, and be equitable or just. We have to admit that CEA alone is not a satisfactory guide to resource allocation in cancer treatment. I argue that health resource allocators need to take into account distributional issues along with cost-effectiveness in the decision to cover or not to cover, or to include significant co-payments. Equity is concerned with the distribution of benefits and costs to different individuals or groups. The benefit maximization associated with the general philosophical moral theory of utilitarianism is routinely criticized for ignoring those considerations (Rawls, 1971). Equity in health care distribution is really complex and illustrates several distinct moral concerns or issues (Brock, 2003b).

One important equity consideration, common to many different accounts of equity and justice, is priority to the worse off (Brock, 2002). Rawls (1971) states that justice of a society is told by how it treats its least well-off members, many religious traditions share this commitment. This is a kind of a concern for reducing inequalities in health between persons or group. Should we give priority to the worst-off cancer patient near death? I believe we cannot since we should focus on who are worse-off in the good that we are distributing. Most importantly, we need to define who worst-offs are. Are the poor or the sickest worst-off? I suggest health allocation to the worst off should be based on levels of health.

Consequently, the aggregation problem occurs when determining which one to take priority: small benefits to a large number of persons versus very large benefits to a few. I am in favor of prioritizing big benefits for a few rather than small benefits for a large population, especially when the cancer treatment or drug is life-saving.

How to improve decision-making process

The U.S. does not have a standard to adopt a limit on cost per QALY and Medicare cannot consider the cost of medical care when deciding if a particular treatment will be paid for by Medicare since Medicare act specifies coverage must be provided for “reasonable and necessary” services. Further, Medicare fails to consider the opportunity cost of the treatments, but this does not guarantee the highest health benefit. In fact, this results in using health resources on inefficient treatments with an unfair distribution. However, NICE in UK does cost-effectiveness analysis on new interventions and use a cap of approximately £30,000 per QALY for recommendations to the National Health Service for coverage. I believe that this is a way to announce the public that you as a government prioritize to have the highest health outcome given the limited resource and it is an objective criterion to decide among different health services for coverage.

As a first step, U.S. needs to launch an independent agency to conduct research on cost and effectiveness of new health technologies and make recommendations to the health decision makers whether those technologies are safe and effective enough to be reimbursed. Moreover, they need to announce a cut-off point based on CEA and make decision accordingly. Therefore, health technology companies cannot invest on high cost cancer treatments and drugs with moderate benefit. This will help reach a consensus among interest group since the system puts an objective criterion for efficient allocation of health resources.

Secondly, Medicare act needs to be redesigned in such a way that Medicare will be authorized to negotiate prices with pharmaceutical

companies, as well as be permitted to refuse coverage on grounds of cost-effectiveness. This will pull down the drug prices and open space for covering other drugs. Pharmaceutical industry will object, yet the budget will not shrink for the drugs, only the composition will change with lower prices.

In terms of ethical perspective, one QALY will have the same social value regardless of the age of the recipient (Gold et al, 1996). I propose that the use of age weighting that gives less value to benefits for the elderly than for younger is often accepted as unjust age discrimination. Moreover, as Daniels (1988) argued, all persons are treated the same at comparable stages of their lives regarding the value of extending their lives, and so the use of QALYs would not constitute unjust age discrimination comparable to gender, ethnic or racial discrimination (Daniels, 1988). Furthermore, CEA will support using resources to affect the so-called social determinants of health rather than using those resources on healthcare to treat disease.

Finally, together with those policy changes, government programs will differentiate the co-payments for cancer treatments or drugs based on ability to pay. This will ensure equal opportunity to health services and let worse-off groups access to health services, hence improve health outcomes. High-income earner will oppose, but we have to keep in mind that health is a right for all people.

Conclusion

Limited resources exert great burden on health resource allocation together with the rise in healthcare spending. Today cancer is the second most common cause of death in U.S. and many cancer treatments offer only limited benefits with very high costs. That's why it is inevitable to make choices among competing treatments. U.S. does not have an objective measure to evaluate the value of cancer treatments while deciding about coverage and the standard is whether the treatment is reasonable and necessary. I argue that this system not only triggers increasing costs but also lacks opportunity cost, particularly results in

the unfair distribution of health resources. As a solution, we need to develop a system having a mixture of cost-effectiveness analysis and ethical issues. First, a new agency must be established to make CEA for new health technologies and assign a cut-off point. Then, Medicare should have the power to negotiate the drug prices and determine the benefit package based on cost per QALY. Finally, the new system will take into account the ethical perspectives and assure fair opportunity, as well as give priority to the worst-off.

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